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## SECTION E: 510(k) SUMMARY K013203

This summary of safety and effectiveness information is submitted in compliance with 21CFR807.92.

July 13, 2001

**Submitter Information:**
Polymer Technology Systems, Inc.
7736 Zionsville Road
Indianapolis, IN 46268

**Contact Person**: Margo Enright
**Phone Number**: 317-870-5610
**FAX Number**: 317-870-5608

**Trade Name:**
BioScanner Beyond Glucose Test Strips

**Common Name:** Glucose test system

**Panel:** Clinical Chemistry 75

**Product Code**: NBW

**Device Classification:** Class II

**Intended Use**
The BioScanner Beyond Glucose test system is intended to be used to measure glucose by healthcare professionals in whole blood and by individuals with diabetes at home in fingerstick whole blood. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, idiopathic hypoglycemia and pancreatic islet cell tumors.

**Device Description**
Glucose in the whole blood sample reacts with glucose oxidase and ferricyanide. The reaction liberates electrons, which produce a small electrical current. The BioScanner Beyond reads the current produced across two electrodes and converts current into glucose concentration.

**Predicate Device Information**

**STATEMENT OF SUBSTANTIAL EQUIVALENCE**

Polymer Technology Systems, Inc., intends to introduce into commercial distribution the BioScanner Beyond Glucose Test Strips for the quantitative determination of Glucose in human whole blood. The BioScanner Beyond Glucose Test Strips are substantially equivalent to the predicate device noted below.

| | |
|---|---|
| Name: | Accu-Chek Comfort Curve Test Strips |
| Device Company: | Roche Diagnostics |
| 510(k) Number: | K 982002 |

**Similarities and Differences (Predicate and BioScanner Beyond Glucose)**

Similarities

- Both systems measure Glucose concentrations in blood.
- Both systems provide a result that correlates to the laboratory plasma glucose result.
- Both systems are calibrated with a glucose hexokinase laboratory method as the reference.
- Both use the same testing principle (amperometric method) in which a small current produced in a chemical reaction is measured and converted into a glucose result in concentration.
- Both reagents are similar in their composition in that both use a glucose oxidase reaction. The current is measured and converted into glucose concentration and reported in mg/dL
- The predicate method requires an Accu-Chek code chip to access the lot code information..
  The BioScanner Beyond Glucose Test Strips contain a lot specific memory chip in the same package with the strips.

Differences

- The BioScanner Beyond Glucose Analyzer requires about one-half of blood sample volume that the Accu-Chek Advantage requires
- The BioScanner Beyond Glucose Analyzer has a display screen that is about 7% larger than the Accu-Chek Advantage

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Margo Enright
Manager of Clinical Affairs
Polymer Technology Systems, Inc.
7736 Zionsville Road
Indianapolis, IN 46268

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Re: K013203
Trade/Device Name: Bioscanner Beyond Glucose Test System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Test System
Regulatory Class: II
Product Code: NBW, CGA
Dated: September 24, 2001
Received: September 25, 2001

Dear Mr. Enright:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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510(k) NUMBER (IF KNOWN): K013203

DEVICE NAME: ~~BioScanner Beyond Glucose Test System~~

INDICATIONS FOR USE:

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Ian Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K013203

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ (Per 21 CFR 801.109)

OR

Over-The-Counter-Use X (Optional Format 1-2-96)